

meant these patients had greatest propensity for quality-of-life improvements and QALY gains, resulting in the public subsidy recommendation in this patient subgroup by the PBAC in Australia. **CONCLUSIONS:** Patients using MOCs with a base-line ACQ-5 ≥ 2.0 or AQLQ ≤ 5.0 are those in whom OM shows optimal cost-effectiveness in the Australian healthcare environment.

PRS31

ECONOMIC EVALUATION OF INDACATEROL IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) FROM THE PUBLIC PAYER PERSPECTIVE IN BRAZIL

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OBJECTIVES: To assess the cost-effectiveness of indacaterol in comparison to tiotropium and formoterol from Brazilian public healthcare system perspective. **METHODS:** A Markov model was designed to project costs and outcomes associated with disease progression of patients with COPD over 3-years time horizon. The model health states are divided by severity of COPD (mild, moderate, severe and very severe) with each of these states divided into three states: no exacerbation, non-severe and severe exacerbations. The target population consists of patients with moderate or severe COPD, and the health states for mild and very severe COPD are included to account for those who improve in first cycle to the mild state and those who progress to very severe state over time. Efficacy data and exacerbation rates were obtained from the pivotal trials. Mortality data for COPD-specific states are based on study by Rutten-van Mölken et al. COPD related medical resource utilization patterns were assessed through clinical experts' panel. Unit costs were extracted from Brazilian official lists. Outcomes are expressed as life years gained (LYG). One-way sensitivity analysis was performed. Annual discount rate of 5% was applied both to costs and outcomes. **RESULTS:** Base case analysis estimated incremental LYG for indacaterol of 0.010 vs. formoterol and 0.006 vs. tiotropium. Indacaterol was cost-saving as compared to tiotropium (incremental cost of -2,667BRL). Comparing to formoterol, the projected ICER was 25,458BRL per LYG. The variables that most influenced the results were time horizon, mortality rates and baseline population. **CONCLUSIONS:** Indacaterol is a valuable alternative for COPD patients, being a cost-saving treatment vs. tiotropium with incremental clinical benefits and lower costs. Versus formoterol, indacaterol has incremental benefit, at a reasonable incremental cost.

PRS32

COST-EFFECTIVENESS OF OMALIZUMAB IN SEVERE UNCONTROLLED ALLERGIC ASTHMA USING RCT AND REAL-WORLD EVIDENCE IN THE DUTCH SETTING

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OBJECTIVES: The objective of this analysis was to compare results of two cost-effectiveness analyses for omalizumab added to standard therapy in severe allergic asthma patients using an RCT (INNOVATE) compared to a real-world, prospective observational study (EXPERIENCE). **METHODS:** A Markov model was developed to examine the cost-effectiveness of add-on omalizumab versus standard care from the perspective of the Dutch health care system over a patient's lifetime. Efficacy data for clinically significant (CS) exacerbations and resource use (hospital admissions, unscheduled physician visits and emergency visits) were derived from INNOVATE or Dutch patients enrolled in EXPERIENCE. Data from each were projected to lifetime with discounted future costs (4%) and outcomes (1.5%). **RESULTS:** For the EXPERIENCE study, the modelled direct medical costs for patients on standard therapy were €77,615, of which 75% was for exacerbation control versus €133,475 for standard therapy + omalizumab, of which 38% was for exacerbation control. Patients on omalizumab had more QALYs than those on standard therapy alone, 12.05 versus 10.47. The resulting ICER was €35,257/QALY for the EXPERIENCE study. The INNOVATE costs were lower in both treatment arms: €22,499 for standard therapy and €58,666 for standard therapy + omalizumab. Costs were lower due to lower rate of CS exacerbations in the RCT where patients had been under best possible control at trial entry. QALYs were similar to the EXPERIENCE study 12.05 and 10.91, respectively; resulting in €31,802/QALY. **CONCLUSIONS:** Decision-makers are often presented with cost-effectiveness evidence from RCTs although they prefer to base decisions on real-world data are preferred. This study is one the first to include both in a re-evaluation dossier. It showed differences in patient characteristics (exacerbation rates and resource use) between the RCT and observational study. However it confirmed the value of omalizumab with similar ICERs, indicating that omalizumab is cost effective in both settings.

PRS33

A COST-EFFECTIVENESS ANALYSIS OF VARENICLINE VERSUS BUPROPION AND NICOTINE REPLACEMENT THERAPY IN GREECE

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OBJECTIVES: To evaluate the cost-effectiveness of varenicline compared to bupropion and nicotine-replacement therapy (NRT) from a third-party payer (Social Insurance Fund) perspective in Greece. **METHODS:** The Benefits of Smoking Cessation on Outcomes (BENESCO) Markov model was applied to calculate the long-term health and economic benefits of smoking cessation, simulating the incidence and outcomes of smoking-related morbidities to a hypothetical cohort of patients (age- and gender-representative of the Greek population) making a single quit attempt. Demographic, epidemiological, treatment efficacy and economic inputs for the modelled cohort were obtained from the literature and publicly available data from public healthcare databases. The model calculated costs and outcomes for a life-

time perspective, discounted at a 3% discount rate and reported in year 2011 fees and prices. Extensive probabilistic sensitivity analysis was performed to test the robustness of the results. **RESULTS:** The cohort consisted of 819,709 current smokers making a quit attempt. The respective 1-year continuous abstinence rates were 22.5%, 15.5% and 15.4% for quitters under varenicline, NRT and bupropion. For a lifetime horizon, varenicline prevented in total 7652 and 7609 additional cases of smoking-related disease (coronary heart disease, stroke, lung cancer, chronic obstructive pulmonary disease) versus NRT and bupropion, respectively. Moreover, varenicline led to a gain of 21,219 QALYs (16,955 life years) and 21,099 QALYs (16,859 life years) for the cohort, compared to NRT and bupropion. Taking direct costs into account, varenicline produced cost-savings against both comparators for the lifetime as well as for shorter (20-year) timeframes of analysis. The probabilistic sensitivity analysis corroborated the study outcomes. **CONCLUSIONS:** Taking into account the Social Security perspective in Greece, varenicline was a dominant smoking cessation strategy compared to NRT and bupropion, reducing both treatment costs and smoking-related morbidity.

PRS34

COST-EFFECTIVENESS OF ROFLUMILAST (DAXAS®) IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN SPAIN

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OBJECTIVES: To estimate the cost-effectiveness of roflumilast (Daxas®) versus the most prescribed drug combination in Spain in the treatment of adult patients with severe chronic obstructive pulmonary disease (COPD) with a history of frequent exacerbations. **METHODS:** A Markov model was constructed to estimate the life time cost-effectiveness of roflumilast plus a long acting muscarinic antagonist (roflumilast + LAMA) versus the combination of LAMA with a long-acting beta agonist plus and an inhaled corticosteroid (LAMA + LABA/ICS). Outcomes were expressed as the incremental cost per exacerbation avoided from the Spanish National Health System perspective using a life-time horizon (30 years). Other health outcomes in the model include quality-adjusted life year (QALY) gained and life years (LY) gained. The key inputs to the model are based on roflumilast pivotal clinical trials and published epidemiological and population data. Uncertainty in the model's parameters was examined by sensitivity analysis. **RESULTS:** The results of the economic analysis have demonstrated that over the lifetime of the treatment of patients with severe COPD and associated chronic bronchitis with a history of frequent exacerbations, the roflumilast + LAMA strategy will cost 3468 € less than using LAMA + LABA/ICS. Over a lifetime a patient treated with a roflumilast + LAMA is estimated to have 1.23 exacerbations less and 0.129 more QALYs than a patient treated with LAMA + LABA/ICS. Therefore, the roflumilast treatment arm appears to be the dominating option. The sensitivity analyses showed that the variable that has the most impact on the ICER results is the relative risk of exacerbations. **CONCLUSIONS:** Roflumilast + LAMA offers a cost-effective option for the maintenance treatment of severe COPD associated with chronic bronchitis in patients with a history of frequent exacerbations compared with LAMA + LABA/ICS.

PRS35

ECONOMIC EVALUATION OF INDACATEROL VERSUS TIOTROPIUM OR FORMOTEROL FOR PATIENTS WITH MODERATE TO SEVERE COPD IN GREECE

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OBJECTIVES: Evaluate the cost-effectiveness of indacaterol (Onbrez Breezhaler, 150µg & 300µg) against tiotropium (Spiriva, 18µg) or formoterol (Foradil, 12µg twice daily) respectively. **METHODS:** A Markov model was developed describing each COPD disease severity stage based on pre-bronchodilator FEV₁ measurements reported in the indacaterol clinical trials (INVOLVE & INHANCE). The outcomes assessment criteria were Quality-Adjusted Life-Years (QALYs), Life Years Gained (LYG) and exacerbation rates. A 3-year time horizon was used for the cost-utility analysis (CUA) and a lifetime (25 year) time horizon was used for the cost-effectiveness analysis (CEA). Discount rates of 3.5% were set for both costs and outcomes and univariate sensitivity analyses were conducted. Resource utilization was based on Greek published data and relevant costs on official NHS prices. **RESULTS:** The mean number of QALYs per patient in the three-year CUA was 2.152 in the indacaterol 150µg arm and 2.144 in the tiotropium arm, resulting in 0.0078 QALYs in favor of indacaterol; the total costs per patient were €9,717 in the indacaterol arm and €9,853 in the tiotropium arm, resulting in €136 savings in favor of indacaterol, gaining the dominant position (lower total costs, better outcomes). The CEA over the lifetime is similarly dominant with 10.213 LYG for indacaterol and 10.119 LYG for tiotropium and a lower cost per patient for indacaterol. The CUA comparing indacaterol 300µg and formoterol also resulted in indacaterol dominating formoterol with an incremental QALY of 0.017 (2.149 and 2.132 respectively) and a cost saving of €48.23 compared to formoterol over 3 years. Similarly, indacaterol dominates the CEA over a life time. Regarding exacerbation rates, although very similar outcomes appeared among treatments, COPD treatment was less costly with indacaterol against all other comparators. **CONCLUSIONS:** For patients with moderate to severe COPD, indacaterol represents a cost-effective treatment and is potentially cost saving for the Greek NHS.

PRS36

THE COST-EFFECTIVENESS OF STEP DOWN FROM HIGH DOSE ICS/LABA COMBINATION THERAPY IN ASTHMA IN THE UK SETTING

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